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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,978	02/06/2002	Eric E. Swayze	IBIS-0403	1815

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EXAMINER

HABTE, KAHSAÿ

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 07/02/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,978

Applicant(s)

SWAYZE ET AL.

Examiner

Kahsay Habte, Ph. D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 06 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-21 and 63-97 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-21 and 63-97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8. 6) ☐ Other:

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DETAILED ACTION

1. Claims 1, 3-21 and 63-97 are pending.

Election/Restriction

2. Applicant's election of Group I, Claims 1, 3-21 and 63-97 in Paper No. 7 is acknowledged.

Information Disclosure Statement

3. Reference 7 in IDS form PTO 1449 was not initialed because of the following reasons:

- (a). Applicants did not specify the database used for the search
- (b). Applicants did not explain the type of strategy that was used to obtain the results.

Specification

4. The specification is defective because on page 40 (line 4) the term "(VENDOR?)" is incorrect. Since said term is making the sentence incomplete. It is recommended that applicants supply the vendor's name or delete the term "(VENDOR?)" from the sentence.

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Abstract

5. The abstract is defective because the phrase "novel benzimidazoles" is too broad. It is required that applicants draw the chemical structure or name the compounds.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

✓
Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Helsley, Grover Cleveland. (GB 1354554 published on May 30, 1974). Cited reference discloses 2-(4-piperidiny)benzimidazole on page 3 (lines 1-9) of the specification (see Preparation 1). Said species is the same as applicants when applicant's compound of Formula I has the following substituents:

R1 = H, Q1 = Q2 = CH, and Q4 = N.

Note that Q3 = CR20 is assumed to represent Q3 = CH, since R20 is not defined.

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7. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lubish et al. (DE 19916460 A1). Cited reference discloses on page 12 of the specification three

species that are the same as applicants namely:

2-(piperidinyl)-4yl-benzimidazole-4-carboxamide

2-(piperidinyl)-4yl-benzimidazole-4-carboxylic acid, ethyl ester

2-(piperidinyl)-4yl-benzimidazole-4-carboxylic acid, hydrazide.

Said species are the same as applicants when applicant's compound of Formula

✓ I has the following substituents:

R1 = H, Q1 = Q2 = CH, and Q4 = N.

Note that Q3 = CR20 is assumed as Q3 = -C(O)-NH-NH2, -C(O)-O-Ethyl, or -C(O)-NH2, since R20 is not defined.

8. Claim 63 is rejected under 35 U.S.C. 102(b) as being anticipated by Ogura et al. (Journal of Medicinal Chemistry, 1972, Vol. 15, No. 9, pages 923-926). Said reference teaches the synthesis of compounds 10a, 10b and 10c (Table V on page 925) as indicated below:

10a 2-amino-N,N-dimethyl-1H-benzimidazole-1-ethanamine

10b 2-amino-N,N-diethyl-1H-benzimidazole-1-ethanamine

✓ 10c 2-amino-N,N-dimethyl-1H-benzimidazole-1-propanamine.

Said species are the same as applicants when applicant's formula I has the following substituents:

R52 = R53 = H, Z = 2-3, R15 and R16 are both methyl or both ethyl.

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9. Claim 73 is rejected under 35 U.S.C. 102(b) as being anticipated by Vlaovic et al. (Bioscience, Biotechnology, and Biochemistry, 1992, 56(2), 199-206). Said reference on page 200 (Table 1, compounds 3₃₂ teaches the synthesis of 5,6-dimethyl-1-[(3-methylphenyl)methyl]-1H-benzimidazole-2-amine and also teaches the synthesis of 4 species that are the same as said species except they have different substituents at 1 position (i.e. Et, Bu-n, hexyl, 3-methoxybenzyl attached at 1-position of the benzimidazole ring, see compounds 3₂₄, 3₂₅, 3₂₇, and 3₃₄).

Said species are the same as applicants when applicant's formula I has the following substituents:

R3 = R4 = methyl

R30 = Et, Bu-n, hexyl, 3-methoxybenzyl, 3-methylbenzyl

R2a = NH₂.

10. Claim 63 is rejected under 35 U.S.C. 102(b) as being anticipated by Chernova et al. (Khimiko-Farmasevticheski Zhurnai (1991), 25(1), pages 50-52). Said reference teaches the synthesis of 5,6-dinitro benzimidazoles substituted by 5-7 membered ring at 2-position.

11. Claims 73-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Jerichel et al. (DE 888032). Cited reference teaches 5,6-dichloro-2-phenyl-1H-

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benzimidazole that is the same as applicants. Said species is the same as applicants

when applicant's formula has the following substituents:

R2a = phenyl, R30 = H, and R3 = R4 = chloro.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-21 and 63-97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. Claims 1 and claims dependent thereon are rejected because the variable "R₂₀" (see on page 2, line 3) is not defined. What is it?

b. In claim 1 (proviso), the term "etser" should read as "ester."

c. In claims 11, 18-19, and 95, there has been recited phrases such as "radicals shown in Scheme 19, *supra*", "radicals shown in Scheme 16, *supra*"..., but it is unclear what type of species they represent. Applicants have to recite the specific compounds or radicals in the claims.


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Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (703) 308-4717. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Kahsay Habte, Ph. D.
Examiner
Art Unit 1624



Mark L. Berch
Primary Examiner
Art Unit 1624

KH
June 30, 2003